

REMARKS

Claims 73-74 were pending in the present application. By virtue of this response, claim 73 has been amended, no claims have been cancelled, and no new claims have been added. Accordingly, claims 73-74 are currently under consideration. Amendment and cancellation of certain claims are not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. No new matter has been added.

Interview Summary

An interview with Examiner Vu was held by telephone on March 28, 2007. In addition to Examiner Vu and Alicia Hager (the undersigned), Catherine Polizzi participated in the interview. Applicants and their representatives would again like to thank Examiner Vu for the courtesy of the telephonic interview.

The subject of the telephonic interview was the Office Action dated January 3, 2007. Claims discussed included claim 73. Potential amendments to claim 73 were discussed in a general manner. In addition, the references cited in the Office Action were discussed. The priority claims that Applicants had previously requested be added and the double-patenting rejections were also discussed during the interview.

Priority Claims

On August 10, 2006, Applicants filed a Supplemental Application Data Sheet which contained priority claims different from those that had been previously recognized by the Office for the application. A Request for Corrected Filing Receipt was also filed at that time, requesting official recognition of the changed priority claims. Copies of those previously filed documents are enclosed herewith. Attention was also drawn in the Amendment filed concurrently to the requested change in the priority claims and to the fact that similar priority claims had previously been denied in an Office Action mailed February 10, 2004, as well as to the relevant law and rules in support of the new priority claims being added.

As indicated in the Supplemental Application Data Sheet filed on August 10, 2006, this application is the National Stage of International Application No. PCT/US98/13272, filed June 26, 1998, which:

- (a) claims the priority benefit of U.S. Provisional Application No. 60/051,021, filed June 27, 1997;
- (b) is a continuation-in-part of U.S. Application No. 08/926,155, filed September 9, 1997; and
- (c) is a continuation-in-part of U.S. Application No. 08/720,756, filed October 1, 1996, which is a continuation-in-part of U.S. Application No. 08/412,726, filed March 29, 1995, which is a divisional of U.S. Application No. 08/023,698, filed February 22, 1993.

Applicants again respectfully submit that the present application is entitled to claim the priority benefit of each of the above-indicated applications under 35 U.S.C. § 119(e) or 35 U.S.C. §§ 120 and 365(c) and 37 C.F.R. § 1.78(a). With respect to the addition of the claim to the priority benefit of U.S. Application No. 08/720,756, filed October 1, 1996, Applicants note that the priority claim is proper since U.S. Application No. 08/720,756 was copending on the international filing date of the present national stage application, June 26, 1998 (see MPEP § 1893.03(c)(III)). It is respectfully submitted that Applicants are entitled to the claim of priority benefit back to February 22, 1993.

The above-indicated priority claims which were submitted in the Supplemental Application Data Sheet filed August 10, 2006, were not previously added as the first sentence in the specification at that time. Inclusion of the priority claims in the first sentence of the specification is not required here since the priority claims were properly submitted in a Supplemental Application Data Sheet. See C.F.R. § 1.78(a)(5)(iii) and MPEP § 201.11(III)(D). Applicants have now, however, by virtue of this Amendment, amended the specification to include the references to the prior-filed applications as the first sentence of the specification after the title.

It is Applicants' understanding from a voicemail left for Alicia Hager (the undersigned) by Mr. Bill Dickson of the U.S. Patent and Trademark Office on May 21, 2007, that the Office has agreed that Applicants are entitled to add additional, earlier priority claims such as those added by Applicants in the present application and that this information has been transmitted by Mr. Dickson to Examiner Michael Hartley who would, in turn, transmit this information to Examiner Vu.

Nevertheless, as of June 27, 2007, the priority claims in question were still not showing in the continuity data on PAIR for this application and no updated Filing Receipt listing the new priority claims had been received by Applicants.

Accordingly, Applicants respectfully request that the Office formally recognize Applicants' requested priority claims on the record and promptly issue an updated Filing Receipt to Applicants that reflects the new priority claims.

Amendments to the Specification

The specification has now been amended to add a section entitled "CROSS REFERENCE TO RELATED APPLICATIONS" to the beginning of the specification that contains the priority claims that were previously made in this application in the Supplemental Application Data Sheet filed on August 10, 2006. No incorporation by reference statement has been included in the newly added section, and Applicants are not incorporating by reference any patent applications that were not already incorporated by reference in the application as originally filed. Accordingly, no new matter is added.

Amendments to the Claims

Claim 73 is amended, without prejudice. This amendment is made to expressly recite that the claimed crosslinking by disulfide bonds in claim 73 refers to crosslinking by *intermolecular* disulfide bonds. Support for this amendment is found, e.g., from line 22 of page 30 to line 2 of page 31, from line 26 of page 34 to line 11 of page 35, and in lines 21-23 of page 46 of the specification. (References to lines and pages of the specification that are provided herein refer to the substitute

specification filed on September 29, 2006.) Claim 73 has also been amended to replace “wherein said protein is albumin, and wherein the albumin is crosslinked by disulfide bonds” with “wherein said protein *comprises* albumin that is crosslinked by intermolecular disulfide bonds” (emphasis added). No new matter is added.

With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and, moreover, have not acquiesced to any rejections and/or objections made by the Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation, continuation-in-part, and/or divisional applications.

Double Patenting Rejections

Claims 73 and 74 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over U.S. Patent Nos. 6,537,579; 5,362,478; 5,498,421; 5,505,932; 5,508,021; 5,512,268; 5,635,207; 5,639,473; 5,650,156; 5,665,382; 5,665,383; 5,916,596; 5,560,933; and 5,439,686.

As discussed with the Examiner during the telephonic interview of March 28, 2007, Applicants will address these rejections, if maintained, when the pending claims are otherwise found allowable. It is Applicants’ understanding from the interview that the Examiner was amenable to such an approach.

Claim Rejections under 35 U.S.C. § 102

Rejection #1 under 35 U.S.C. § 102:

Claim 73 is rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by Violante et al. (U.S. Patent No. 5,741,522) in light of Markus et al. (“The Disulfide Bonds of Human Serum Albumin and Bovine Gamma-Globulin”, J. Am. Chem. Soc., 1957, 79(1): 134-139). Applicants respectfully traverse this rejection.

Claim 73 is directed to an article of manufacture comprising a dry powder or liquid formulation of water insoluble drug and at least one protein, wherein the dry powder or liquid formulation comprises a solid core of water insoluble drug nanoparticles coated with the protein, and wherein the protein comprises albumin that is crosslinked by intermolecular disulfide bonds.

To anticipate a claim, a prior art reference must teach or suggest each and every limitation of the claim. Applicants respectfully submit that the Violante et al. reference, in light of the Markus et al. reference, does not anticipate claim 73, because the references fail to disclose or suggest all elements of claim 73. The Violante et al. reference, even in light of the Markus et al. reference, fails to disclose or suggest an article of manufacture comprising a dry powder or liquid formulation of water insoluble drug and at least one protein, wherein the formulation comprises a solid core of water insoluble drug nanoparticles coated with the protein, and wherein the protein comprises albumin that is crosslinked by *intermolecular* disulfide bonds. For instance, as noted by the Examiner, the Violante et al. reference “does not disclose that the albumin is crosslinked by disulfide bonds” (page 5 of the Office Action), and although the Examiner has stated that the Markus reference “teaches that albumin has disulfide bonds that are cross-linked” (page 5 of the Office Action), the Markus et al. reference only refers to disulfide bonds that are *intramolecular*.

Since Violante et al. in light of Markus et al. does not teach or suggest each and every element of claim 73, Applicants respectfully request that the rejection of claim 73 under 35 U.S.C. § 102(e) be withdrawn.

Rejection #2 under 35 U.S.C. § 102:

Claims 73 and 74 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by Liversidge et al. (U.S. Patent No. 5,399,363) in light of Markus et al. Applicants respectfully traverse this rejection.

Claim 73 is as described above in response to the rejection over the Violante et al. reference. Claim 74 is dependent upon claim 73 and therefore incorporates all limitations of claim 73.

To anticipate a claim, a prior art reference must teach or suggest each and every limitation of the claim. Applicants respectfully submit that the Liversidge et al. reference, in light of the Markus et al. reference, does not anticipate claim 73, because the references fail to disclose or suggest all elements of claim 73. The Liversidge et al. reference, even in light of the Markus et al. reference, fails to disclose or suggest an article of manufacture comprising a dry powder or liquid formulation of water insoluble drug and at least one protein, wherein the formulation comprises a solid core of water insoluble drug nanoparticles coated with the protein, and wherein the protein comprises albumin that is crosslinked by *intermolecular* disulfide bonds. As noted by the Examiner, the Liversidge et al. reference “does not disclose that the albumin is crosslinked by disulfide bonds” (page 5 of the Office Action). In fact, lines 57 to 59 of column 4 of the Liversidge et al. reference state, “Furthermore, the individually adsorbed molecules of the surface modifier are essentially free of intermolecular crosslinkages.” As already noted above, the Markus et al. reference only refers to disulfide bonds that are *intramolecular*.

Since Liversidge et al. in light of Markus et al. does not teach or suggest each and every element of claims 73 and 74, Applicants respectfully request that the rejection of the claims under 35 U.S.C. § 102(e) be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims, and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **420052000126**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: July 3, 2007

Respectfully submitted,

By


Alicia J. Hager

Registration No.: 44,140

MORRISON & FOERSTER LLP
755 Page Mill Road
Palo Alto, California 94304-1018
(650) 813-4296